DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 21, 2015

MegaGen Implant Co., Ltd
c/o Ms. Megan Holden
Kodent, Inc.
325 N. Puente St., Unit B
Brea, California 92821

Re: K150537
Trade/Device Name: MiNi Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 16, 2015
Received: June 22, 2015

Dear Ms. Holden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K150537

Device Name: MiNi Internal Implant System

Indications for Use:

The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:

- The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed loading.

Prescription Use X AND/OR Over The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

(K150537)

This 510(k) Summary is being submitted in accordance with requirements of 21 CFR Part 807.92.

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Device Information:
Device Name: MiNi Internal Implant System
Classification Name: Endosseous Dental Implant
Classification: Class II
Product Code: DZE
Subsequent Product Code: NHA
Regulation number: 21 CFR 872.3640
Date Prepared: 7/17/2015

General Description

MiNi Internal Implant System is composed of MiNi Internal Fixtures, abutments, and surgical instruments. The dental fixtures are made of CP Ti Grade 4 designed for use in dental implant surgery. This system is used as two stage surgery, root-form dental implants, associated with abutment systems, which provide the clinician with the screw and cement retained restoration for multi-mount options.
The fixtures are available in diameters of 3.0mm, 3.4mm and lengths of 8.0mm, 9.5mm, 11.0mm, 12.5mm, and 14.5mm. The fixtures, abutments, and surgical instruments are produced and packaged separately. The Surface treatment for this device is S.L.A (Sand-blasted, Large grit, Acid-etched).
This system includes various abutments, such as Abutment Screw, Cover Screw, Healing Abutment, EZ Post, Angled Abutment, Milling Abutment, Solid Abutment, Temporary Abutment, Impression Coping, Plastic Impression Coping, Guide Pin, Lab Analog, and Meg-Rhein Abutment. These abutments are compatible with MiNi Internal Fixtures.

Indication for use

The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:

- The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed loading.

Predicate devices

- Primary Predicate Device : OsseoSpeed™ Plus (K120414)
- Reference Predicate Device : XPEED AnyRidge Internal Implant System (K140091)

Substantial Equivalence Comparison

The MiNi Internal Implant System is similar designs and dimensions, and has the same material, intended use, and technological characteristics as the identified primary predicate device (K120414). The MiNi Internal Implant System is similar in fundamental scientific technology, and has the same material, surface treatment to the reference predicate device (K140091). When compared with predicate device, no new questions of substantial equivalence have been raised for the MiNi Internal Implant System.

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device**
510(k) Number	K150537	K120414	K140091
Device Name	MiNi Internal Implant System	OsseoSpeed™ Plus	XPEED AnyRidge Internal Implant System
Manufacturer	Megagen Implant Co., Ltd.	Astra Tech AB	Megagen Implant Co., Ltd.
Indications for Use	The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: • The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. • Immediate placement in extraction sites and in	Implants: The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or	The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate

Indications for Use (continued)	situations with a partially or completely healed alveolar ridge. • It is intended for delayed loading.	completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors. Abutments: Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Atlantis Abutments: The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.	loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.

Design		MiNi Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex	-Single-stage or two-stage - Single-tooth and/or multiple tooth applications - OsseoSpeed^{TM} Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisor Internal Double Hex	XPEED AnyRidge Internal Implant System, abutments and accessories have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments Internal Hex
Material		CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)	CP Ti Grade 4 (ASTM F67)
Sterilization		Gamma sterilization	Gamma sterilization	Gamma sterilization
Fixture Diameter		Internal Type: Ø3.0, 3.4mm	Internal Type: Ø3.0, 3.5, 4.2, 4.8, 5.4mm	Internal type 4.0 ~ 8.4mm
Fixture Height		Internal Type: 8.0, 9.5, 11.0, 12.5 14.5mm	Internal Type: 6.0 – 17.0mm (6.0mm height excluded for Ø3.0, 4.2, 4.8mm and 17.0mm height excluded for Ø3.0, 5.4mm)	Internal type: 7.7 ~ 14.4mm
Abutment	**Diameters**	Ø3.0 ~ 3.5mm	Ø3.0 ~ 5.4mm	Ø4.0 ~ 10.0mm
	Materials	Ti-6Al-4V ELI	-	Ti-6Al-4V ELI, CP Ti Grade 4
Angulations of Angled abutments		15°	15° ~ 30°	15°, 25°
Product Code		DZE, NHA	DZE, NHA	DZE, NHA
Surface Treatment		Sand-blasted, Large grit, Acid-etched (S.L.A)	Resorbable Blasting Media (R.B.M) and fluoride coating	Sand-blasted, Large grit, Acid-etched (S.L.A)

The differences in indications between the MiNi Internal Implant System and primary predicate device (K120414) do not raise new questions of substantial equivalence because they are selected as a subset of the primary predicate. The MiNi Internal Implant System removed the indications of one-stage surgery, immediate loading, and soft bone clinical use compared to the primary predicate (K120414). Thus, the proposed indications do not increase risk nor change the intended use of the device and are found to be substantially equivalent.

Non-Clinical Test Data

Sterilization validating testing has been performed in accordance with ISO 11137-1, ISO 11137-2,

ISO 11137-3, ISO 11737-1, and ISO 11737-2 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

The fatigue test was performed on the subject device in accordance with ISO 14801:2007 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The worst case scenario was chosen based on the FDA guidance “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device.

Testing Item	
Conducted test on the subject device	Fatigue Test Sterility test
Not conducted test on the subject device	Biocompatibility test: Cytotoxicity Sensitization Irritation or Intracutaneous reactivity Systemic toxicity Sub-chronic Toxicity Genotoxocity Implantation
	Surface Analysis
	Residue Analysis

Biocompatibility Test, surface analysis, and residue analysis have not been conducted because the subject device has the same material, surface treatment, and manufacturing process as the reference predicate device (K140091). There is no difference between the subject and predicate device. There is no additional testing conducted on the subject device.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Megagen Implant Co., Ltd. concludes that the MiNi Internal Implant system is substantially equivalent to predicate devices as described herein.